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EXAMINER	
WOOLWINE, SAMUEL C	
ART UNIT	**PAPER NUMBER**
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,428	PETERS, LARS-ERIK	
	Examiner	Art Unit	
	Samuel Woolwine	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007 and 03 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 36-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

This application has been transferred to Examiner Samuel Woolwine, whose contact information appears below.

Claims 1-42 are pending in the application. Based on Applicant's election of the product claims (Group II, claims 15-35) in the response filed 06/21/2006, claims 1-14 and 36-42 are withdrawn as being directed to a non-elected invention.

Claims 15-35 were rejected in the Office action dated 08/28/2006.

Election/Restrictions

It is noted that in response to a restriction requirement dated 6/21/2006, Applicant elected Group II (product claims) without traverse, and added new claims 39-42 that are directed to a patentably distinct invention (i.e. method of use for the elected product claims). These claims were not addressed in the previous Office action dated 8/28/2006.

Claims 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/21/2006.

Response to Arguments

The rejections made under 35 U.S.C. 112, 2nd paragraph in OA 08/28/2006 are withdrawn in view of Applicant's amendments.

Applicant's arguments with respect to the rejections under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection. This action is NON-FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is vague and indefinite what is meant by the "15" preceding the term "polystyrene". The specification was searched for another occurrence of the term "polystyrene" for clarification, and the only other occurrence of "polystyrene" was found in original claim 6 (which did not contain the "15"). If the occurrence of "15" is intentional, Applicant is required to explain its meaning without the introduction of new matter. For example, Applicant may submit evidence that the meaning of "15 polystyrene" is an art recognized form of polystyrene. Otherwise, Applicant may overcome this rejection by simply deleting "15".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19, 22, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Asada et al (WO 00/14218, the March 16, 2000 publication of international application PCT/JP99/04815) as evidenced by Mochizuki et al (Journal of Clinical Microbiology, Sept 1999, vol 37, no 9, pp 2936-2942), and Uemori et al (USPN 6,673,578). As the Asada reference was published in Japanese, USPN 6,673,578, which resulted from the national phase entry of PCT/JP99/04815 under 35 U.S.C. 371, will be used as an English translation, and all teachings will be pointed out with reference to the '578 patent.

Asada teaches both a composition for polynucleotide (i.e. DNA) synthesis (beginning at column 3, line 20) and a kit for use in practicing the method (beginning at column 12, line 33).

With regard to claim 15, Asada teaches a kit (column 12, line 33) comprising a thermostable polymerase (column 12, lines 40-45 and line 58; "Taq" is Thermus aquaticus DNA polymerase, which is thermostable), a non-nucleic acid polyanion ("acidic substance": column 13, lines 10-19 and column 9, lines 34-63; for example polyvinyl sulfates, polystyrene sulfates (column 9, line 38), sulfated-fucose-containing polysaccharides, dextran sulfate (column 9, lines 46-47)), and an appropriate polymerase reaction buffer (column 13, lines 31-34). Regarding the limitation "reversibly bound", this is considered to be a recitation of intended use. Furthermore, it is clear from Asada's method that the polymerase and the non-nucleic acid substance (i.e. "acidic substance) are to be used in such a way that they are simultaneously present. Finally, Asada clearly states:

> "The above DNA polymerase, the acidic substance and other reagents may be contained in the kit in a state where each is present as an independent component, or a state in which some of the components are combined, including, for instance, a state in which the components are added to the reaction buffer and the like." (column 13, lines 34-39)

With regard to claim 16, Asada teaches Thermus aquaticus (i.e. Taq; column 12, lines 40-45 and line 58).

With regard to claim 17, Asada teaches dextran sulfate (column 9, lines 43-47).

With regard to claim 18, Asada teaches nucleotide 5'-triphosphates (column 13, line 32).

With regard to claim 19, Asada teaches primers (column 2, lines 48-54 and column 13, lines 50-53, for example).

With regard to claim 22, Asada teaches a composition comprising a thermostable polymerase ("Polymerase A", column 20, line 62; polymerase A is TaKaRa EX Taq DNA polymerase, see column 15, lines 41-49), a non-nucleic acid polyanion ("sodium alginate", column 20, line 63), a polymerase reaction buffer having monovalent cations between 35-60 mM ("50 mM potassium acetate", column 20, lines 60-61; potassium is a monovalent cation), at least one dNTP (see column 20, lines 59-60), a template nucleic acid molecule ("λDNA", column 20, line 61), and appropriate template nucleic acid primers ("primers λ1 and λ2", column 20, line 62).

With regard to claim 32, Asada teaches DNA polymerase ("Polymerase A", column 20, line 62; polymerase A is TaKaRa EX Taq DNA polymerase, see column 15, lines 41-49).

With regard to claims 33 and 34, Taq is derived from Thermus aquaticus, which is a thermophilic Eubacteria.

Claims 22-29, 32 and 35 rejected under 35 U.S.C. 102(b) as being anticipated by Schinazi et al (Antimicrobial Agents and Chemotherapy, 1989, vol 33, no 1, pp 115-117).

With regard to claim 22, Shinazi teaches a composition (a reverse transcription reaction) comprising a thermostable polymerase (HIV-1 reverse transcriptase; see Table 1 and caption), a non-nucleic acid polyanion (dextran sulfate, i.e. DS-8,000 and DS-1,340, see Table 1 and caption and see page 115, column 2, lines 1-2), a polymerase reaction buffer having monovalent cations between 35-60 mM (Shinazi teaches 50 mM KCl, see Table 1 caption; K, i.e. potassium, is a monovalent cation), at least one dNTP (TTP, see Table 1 caption), a template nucleic acid molecule (poly(rA)$_n$, see Table 1 caption), and appropriate template nucleic acid primers (oligo(T)$_{12-18}$, see Table 1 caption).

With regard to claims 23-25, Shinazi teaches dextran sulfate of either 8,000 da or 1,340 da (see Table 1 and caption, see also page 115, column 2, lines 1-2).

With regard to claims 26-29, Shinazi teaches dextran sulfate (see Table 1 and caption) as recited in claim 29, which must therefore satisfy the limitations of claims 26-28, since claims 26-29 are successively dependent and culminate in a group of compounds which includes dextran sulfate.

With regard to claims 32 and 35, Shinazi teaches HIV-1 reverse transcriptase (see Table 1 and caption).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al (USPN 4, 840,941) in view of the 1988 Stratagene Catalog.

With regard to claim 15, Ueno teaches a preparation for polynucleotide synthesis on a target nucleic acid comprising a thermostable polymerase (AMV reverse transcriptase; see Example 1, columns 7-8), a non-nucleic acid polyanion (dextran sulfate; see Example 1, columns 7-8), and an appropriate polymerase reaction buffer (Tris-HCl, pH 8.4; see Example 1, columns 7-8). Regarding the limitation "reversibly bound", this is considered to be a recitation of intended use. Furthermore, it is clear from Ueno's method that the polymerase and the non-nucleic acid polyanion are to be used in such a way that they are simultaneously present.

With regard to claim 17, Ueno teaches dextran sulfate (see Example 1, columns 7-8).

With regard to claim 18, Ueno teaches at least one nucleotide 5'-triphosphate (tritium labeled thymidine triphosphate; see Example 1, columns 7-8).

With regard to claim 19, Ueno teaches at least a pair of primers for the target nucleic acid (Ueno teaches dT_{12-18} primer DNA; see Example 1, columns 7-8; thus dT_{12} and dT_{13} could be considered a pair, as could dT_{12} and dT_{15}, etc).

With regard to claims 20 and 21, Ueno teaches dextran sulfate with a molecular weight in the recited ranges (e.g. dextran sulfate with molecular weight of 5,000; see Example 1, columns 7-8).

Ueno does not teach putting these reagents in the form of a "kit", as recited in claim 15.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the reagents used by Ueno into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Claims 22-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diringer et al (USPN 5,153,181) in view of Jurkiewicz et al (AIDS, 1989, vol 3, pp 423-427).

With regard to claim 22, Diringer teaches a composition comprising a thermostable polymerase (HIV reverse transcriptase, see figures and column 6, lines 43-49), a polymerase reaction buffer having monovalent cations (KCl, K being a monovalent cation; see column 7, lines 42-45), at least one dNTP (see column 7, lines 42-45), a template nucleic acid molecule and appropriate template nucleic acid primers (column 7, lines 45-47 and, for example, figure 1D; since according to column 7, lines 45-47, labeled dTTP was used, it would have been clear that poly(dA) in figure 1D served as the template nucleic acid molecule, while poly(dT) served as the primer). Diringer also teaches a non-nucleic acid polyanion in the composition: dextran sulfate of various molecular weights, chondroitin sulfate, pentosan polysulfate, etc (column 4, lines 28-39, and see column 6, lines 1-22 and the figures).

With regard to claims 23-25, Diringer teaches dextran sulfates with molecular weights of 5000, 8000 and 500000 (see column 4, lines 28-39).

With regard to claims 26-29, Diringer teaches dextran sulfate, as recited in claim 29 (see column 4, lines 28-39), which must therefore satisfy the limitations of claims 26-28, since claims 26-29 are successively dependent and culminate in a group of compounds that includes dextran sulfate.

With regard to claims 30 and 31, Diringer teaches at least one assay in which dextran sulfate of molecular weight of 500000 was used in and HIV RT assay (see

figure 1D, solid squares connected with solid line (see column 6, lines 8-9)). For the reaction having 10^2 µg/ml (see figure 1D), this calculates to 0.2 µM based on the molecular weight of 500000, and thus satisfies the ranges recited in the claims.

With regard to claim 32, Diringer teaches HIV reverse transcriptase (see figures and column 6, lines 43-49).

With regard to claim 35, Diringer teaches HIV reverse transcriptase, which must necessarily be either HIV-1 or HIV-2. To the examiner's knowledge, there are only these two types of HIV.

The only limitation Diringer does not teach is that the polymerase reaction buffer has monovalent cations between 35 and 60 mM (as recited in claim 22). Diringer teaches 80 mM (see column 7, line 43).

Jurkiewicz teaches a polymerase reaction buffer for HIV reverse transcriptase comprising 30 mM KCl (see page 424, last paragraph under "Reverse transcriptase inhibition assay"). Furthermore, Jurkiewicz was performing the same types of assays as Diringer, i.e. testing various polyanionic compounds, including dextran sulfates, chondroitin sulfate, pentosan polysulfate, etc (see table 1) for their effects on HIV reverse transcriptase.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to vary the KCl concentration over the range from 30-80 mM (which completely encompasses the claimed range of monovalent cation). See MPEP 2144.05(I) Overlap of Ranges.

Conclusion

No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

scw

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